Russian Innovative Medicines

November 2016

State Program “Pharma 2020"

activities of Group 2 “Development of Innovative Potential of the Pharmaceutical Industry”

Program purpose:

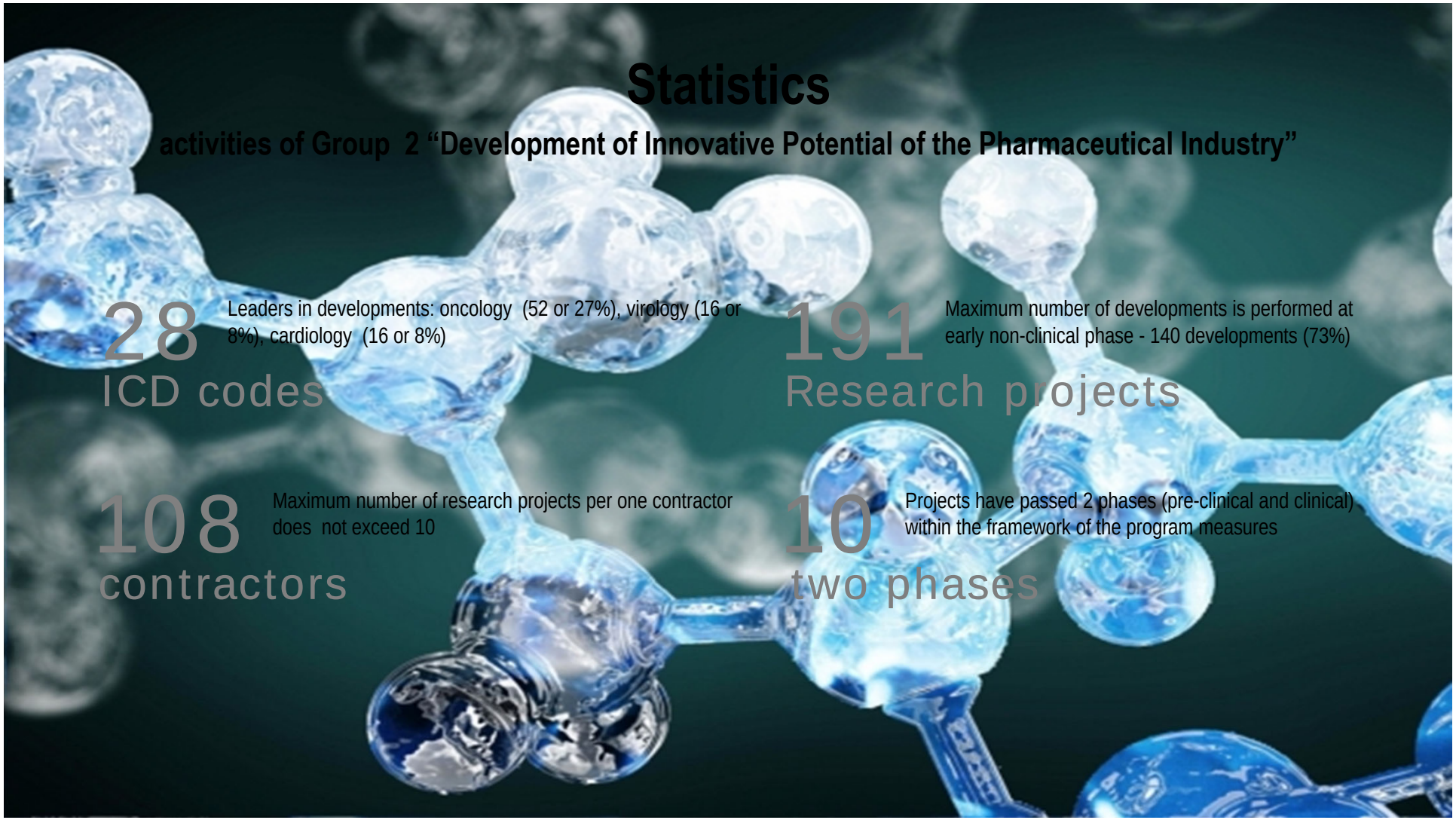
Creation of innovative Russian world-class pharmaceutical and medical industry

Key tasks:

- Creation of scientific and technological potential for the development of innovative drugs
- Provision of pharmaceutical market with home-produced drugs of up to 50%, in monetary terms
- Creation of a mechanism for financing the innovative drugs development
- Growth of small and middle-sized innovative enterprises
- Increase of pharmaceutical product exports

NEXT STEP:

Launch of market mechanism of investments attraction and engaging scientific developments in the production process


Statistics
activities of Group 2 “Development of Innovative Potential of the Pharmaceutical Industry”
28
ICD codes
Leaders in developments: oncology (52 or 27%), virology (16 or 8%), cardiology (16 or 8%)
191
Research projects
Maximum number of developments is performed at early non-clinical phase - 140 developments (73%)
108
contractors
Maximum number of research projects per one contractor does not exceed 10
10
two phases
Projects have passed 2 phases (pre-clinical and clinical) within the framework of the program measures

What organizational mechanisms shall be created?

Growth points

Project office

Organizational mechanism ensuring system operation that promotes commercialization of advanced scientific developments

What has been done?

Intermediate results of project office activity

Selection criteria

A set of criteria taking into account cross-functional task aspect was created

The audit procedure

The development audit methodology was created and testing is carried out by cross-functional working groups

Working groups

5 working groups of experts were created

Support measures

A briefing note on support measures for working with developers

Working groups of experts

The task of the project group is not simply to choose the best project, expert competence of project office allows "pulling up" of the weak points (commercial, profile and juridical) of the projects

Number of working groups 5

Basic composition: three groups (medicine and pharmaceutics, business, patents and intellectual property protection).
The composition is flexibly changed depending on project-specific request

Objectivity: over 30 experts

To obtain maximum results, the expert group activity includes the principle of double checking of the decision by different expert groups

Requirements for experts

Experience, confirmed high expert level, independence and absence of direct interest (in a specific project)

Partners of project office

Северный
Биофармкластер на базе МФТИ

GXP ГИЛС и НП

РОССИЙСКОЕ ТЕХНОЛОГИЧЕСКОЕ АГЕНТСТВО

Sk Сколково


The Procedure of the projects' selection and analysis
Step 1 Collection of materials and expert analysis of the projects, performed by working groups
Step 2 Evaluation of the projects by 3 groups of criteria, with preparation of project profile-questionnaire
Group №1
3 criteria
weight > 0.2
• Innovativeness level
• Development stage
• Competitive environment in the world
Group No.2
3 criteria
weight > 0.05
• Patent type
• Intellectual property protection
• Expert opinion
Group No.3
4 criteria
weight >0.002
• International partnership
• Raw material type
• Raw material availability
• Readiness for industrial operations
Step 3 Selection of developments, as per groups: pilot, additional.
Interaction with developers, preparation of recommendations sheet

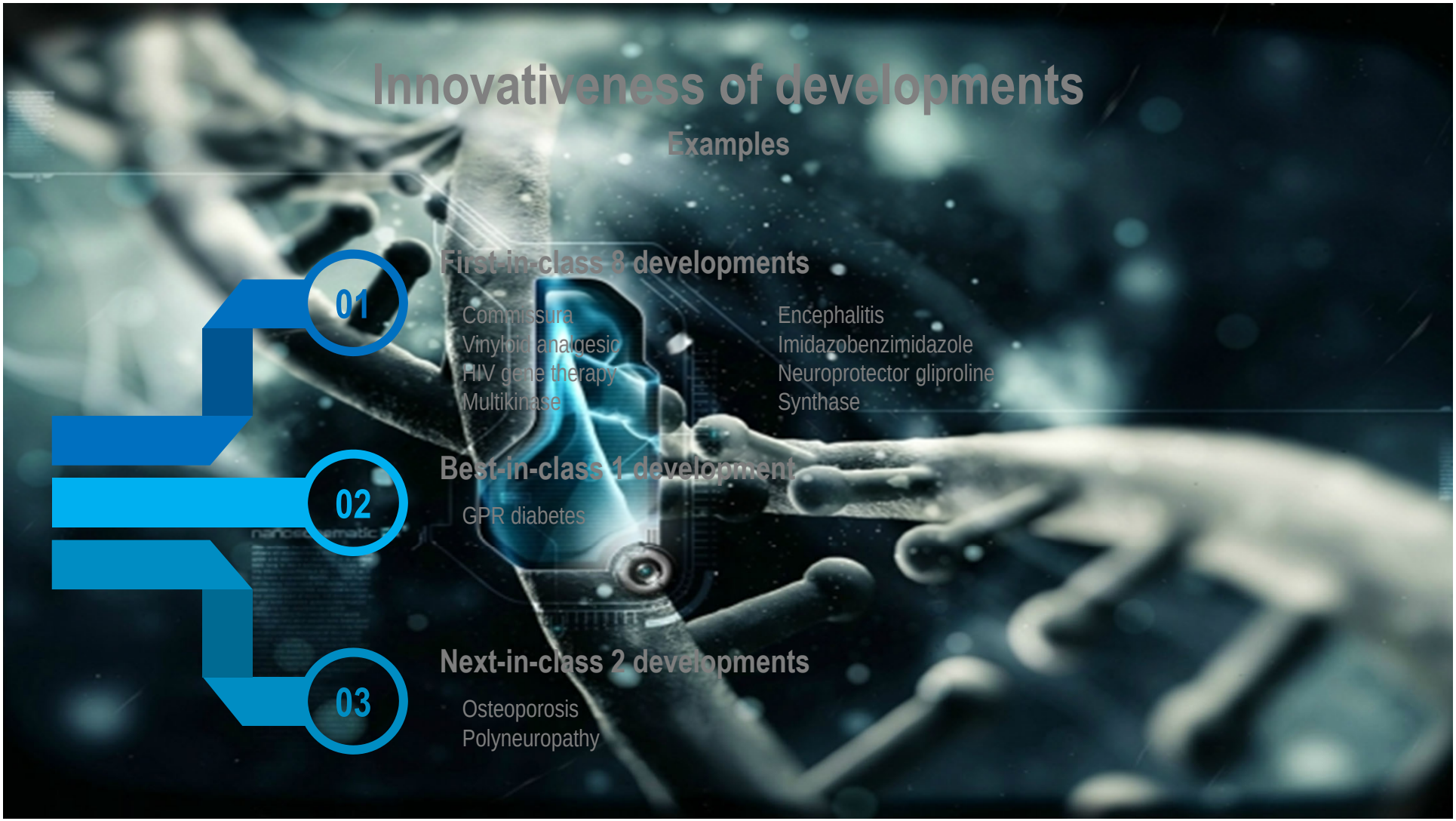
Examples of developments selected within the framework of project office activities

Projects group phase of clinical studies (CS)

Polyneuropathy	Innovative drug for pathogenetic treatment of diabetic distal polyneuropathy Currently, there are no registered drugs for pathogenetic treatment
Osteoporosis	Drug for treatment of bone metastasis of capped tumors and osteoporosis based on hybrid antibody-like osteoclast-activating inhibitory molecule
Commissura	Medicinal slow-release drug for prevention of peritoneal commissura

Projects group phase of pre-clinical studies (PS)

Vinyloid analgesic	Drug resulting in a high level of selectivity and specificity to vanilloid receptor TRPV1. Fundamentally new analgesic specifically acting on the molecular mechanisms of pain generation, with minimal side effects.
Diabetes	Drug acting receptor GPR119, which promotes generation of incretin products, which are lower at type 2 diabetes. It decreases the risk of developing hypoglycaemic reactions.
Multikinase	Anti-leukemic drug, comparable to or greater than edelfozin by activity, at significantly higher and minimal damage to normal cells. The particular importance is the establishment of phosphorus-free alkyl glycerolipids inhibiting substances, which are important for proliferation and survival of leukemia cells
Encephalitis	Biotechnological immunoglobulin replacing serum product derived from donated blood. With high affinity and protective properties, which are hundreds times greater than the protective properties of the commercial immunoglobulin serum.
Imidazobenzimidazole	Drug with the kappa-opioid agonistic activity on the basis of derivative of imidazobenzimidazole, combines the unique pharmacological properties of highly selective kappa agonist and potent analgesic that does not cause respiratory disorders and drug addiction.
Neuroprotector gliproline	Neuroprotector, based on gliproline group of peptides, combines both high performance, duration, speed of onset of effect and absence of negative aftereffects.
HIV gene therapy	Combined gene therapy drug for HIV infection treatment
Synthase	Drug which increases the activity of endothelial NO-synthase


Innovativeness of developments
Examples
01
First-in-class 8 developments
Commissura
Vinyloid analgesic
HIV gene therapy
Multikinase
Encephalitis
Imidazobenzimidazole
Neuroprotector gliproline
Synthase
02
Best-in-class 1 development
GPR diabetes
03
Next-in-class 2 developments
Osteoporosis
Polyneuropathy


Competitive environment
01
There are no analogs with similar mechanism of action, either in the market or in development - 5 projects
Commissura
Vinyloid analgesic
Synthase
Neuroprotector gliproline
Multikinase
02
There are analogs with similar mechanism of action, being at the stage of development - 5 projects
Diabetes
HIV gene therapy
Polyneuropathy
Imidazobenzimidazole
Osteoporosis
03
There are analogs in the market (on sale), but they are protected by patents
1 development
Encephalitis


Protection of intellectual property and the types of patents
11 developments are protected by patents, 6 developments have patents of the Russian Federation and main national patents
01
for the active ingredient 8 developments
Commissura
Polyneuropathy
HIV gene therapy
Imidazobenzimidazole
Vinyloid analgesic
Synthase
GPR diabetes
Encephalitis
02
for the method for producing the active substance 5 developments
Commissura
Polyneuropathy
Vinyloid analgesic
Synthase
GPR diabetes
03
for pharmaceutical composition 5 developments
Commissura
Polyneuropathy
Osteoporosis
GPR diabetes
Neuroprotector gliproline

Raw material: availability and type

Synthetic substance
7 developments

Neuroprotector gliprolline
Imidazobenzimidazole
Multikinase

Commissura
Polyneuropathy

Synthase
GPR diabetes

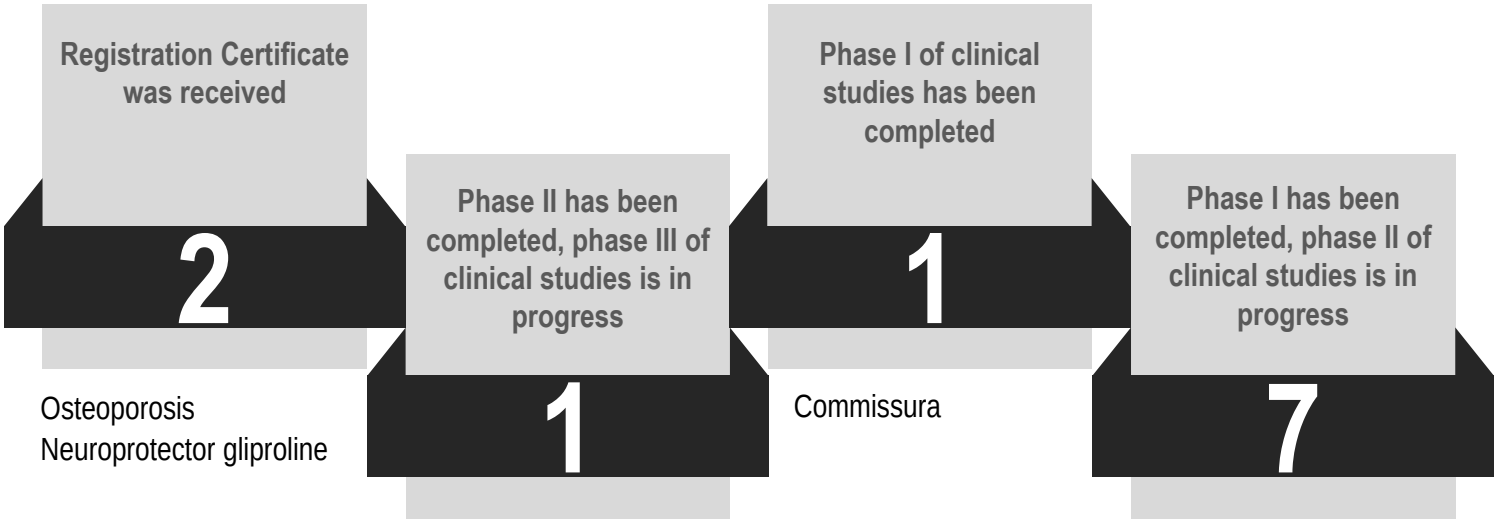
Biotechnological substance
4 developments

Encephalitis
Vinyloid analgesic
HIV gene therapy
Osteoporosis

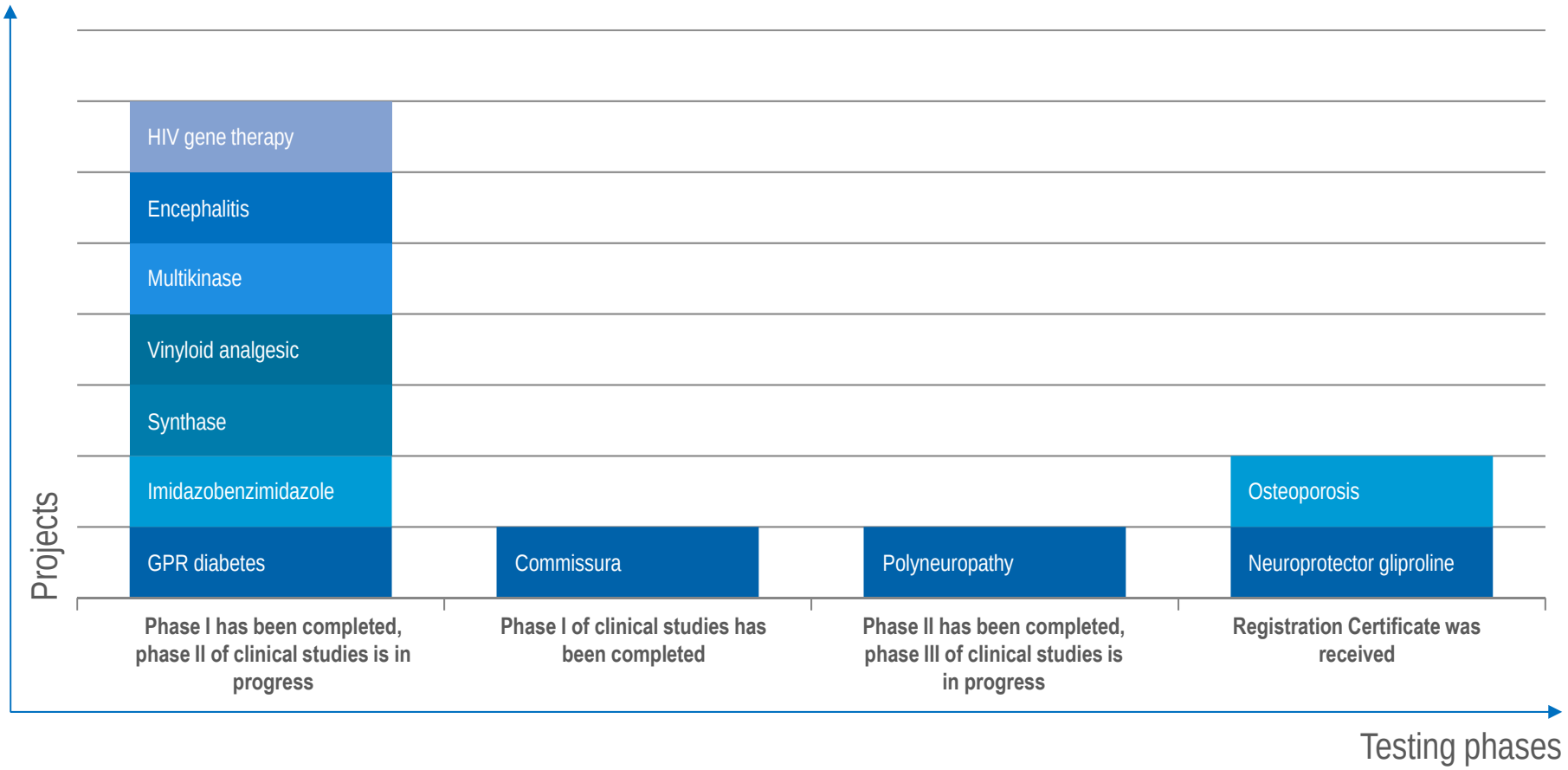
7 developments more than 50% of reagents for receiving substance and finished dosage form, in monetary terms are produced in Russia

Development stages

First group of selected projects



Development stages




Next steps
Projects packaging
Preparation for presentations of a part of the projects - November 2016
01
Creation of methodology
Preparation of the design documentation on operations with the developed methodology November 2016
02
Work with developers
Preparation of recommendations for updating of developments November 2016
03
Interaction with investors
December 2016 -December 2017
Launch of market mechanism, attracting of investments and engaging scientific developments in the production process

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